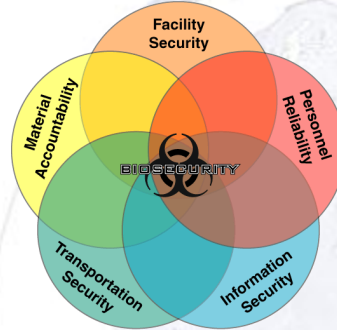




Introduction to Laboratory Biosecurity



EBSA 2009 Pre-Conference Workshop

International Biological Threat Reduction, Sandia National Laboratories, USA
Biosecurity Institute, Lyngby, Denmark
SIPRI, Solna, Sweden

SAND No. 2009-5485C

Sandia is a multiprogram laboratory operated by Sandia Corporation, a Lockheed Martin Company,
for the United States Department of Energy's National Nuclear Security Administration
under contract DE-AC04-94AL85000.



Group Discussion



How do you define **biosecurity**?



A Focus on the Laboratory

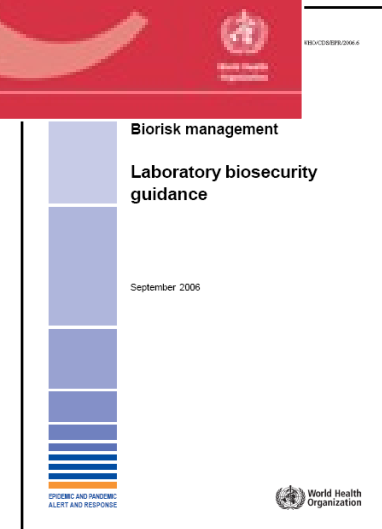
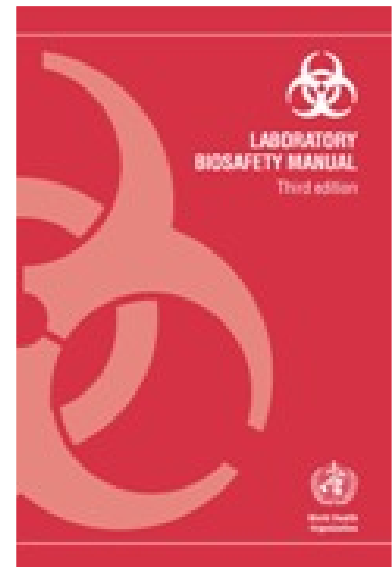


- **Laboratory Biosafety**

Describes the containment principles, technologies, and practices that are implemented to prevent the unintentional exposure to pathogens and toxins, or their accidental release

- **Laboratory Biosecurity**

Describes the protection, control and accountability for valuable biological materials within laboratories, in order to prevent their unauthorized access, loss, theft, misuse, diversion, or intentional release



Source: WHO Biorisk Management: Laboratory biosecurity guidance, September 2006.





Group Activity



What are specific elements of biosecurity?

Write one distinct idea per piece of paper. Write in large lettering.



Laboratory Biosecurity Objectives



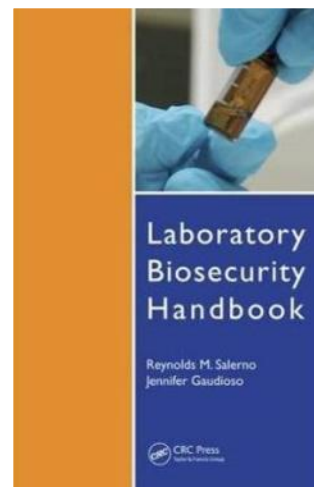
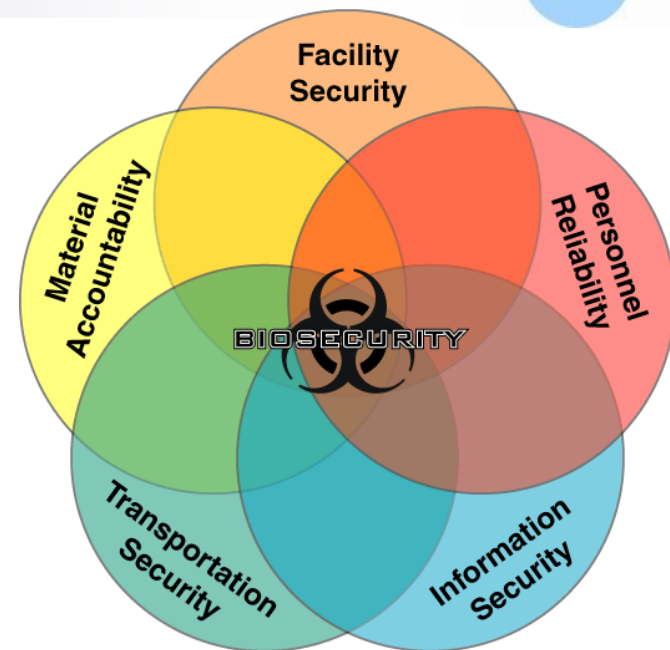
- **Do you limit who may enter your laboratories?**
- **Do you know who works in your laboratories with dangerous pathogens?**
- **Do you trust those persons to conduct their jobs well and responsibly?**
- **Have they been appropriately trained to protect themselves, the environment, and the pathogens?**
- **Do you maintain and control your collections of dangerous pathogens, inside and outside the laboratories?**



Components of a Laboratory Biosecurity System



- **Biosecurity system components**
 - Physical security
 - Personnel security
 - Material handling and control measures
 - Transport security
 - Information security
 - Program management practices
- **Each component implemented based on results of risk assessment**





Group Activity



Group your biosecurity elements into their components.

Biosecurity components:

Physical security

Personnel security

Material control & accountability

Information security

Transportation security

Program management



Elements of a Physical Security System



- **Graded protection**
- **Access control**
- **Intrusion detection**
- **Response force**





Physical Security Example: Access Controls



- **Mechanism to 'by-pass' security system**

Allow entry of

- **Authorized persons**

Prevent entry of

- **Unauthorized persons**

Allow exit of

- **Authorized persons**

- **How**

Something you have

- **Key**
- **Card**

Something you know

- **Personal Identification Number (PIN)**
- **Password**

Something you are

- **Biometric feature (i.e., fingerprints, face)**

- **Combining factors greatly increases security**

Card
PIN



Biometrics



Elements of a Personnel Security Program



- **Visitor Controls**
- **Personnel Screening**
- **Badges**
- **Training**





“Somebody once said that in looking for people to hire, you look for three qualities: integrity, intelligence, and energy. And if they don't have the first, the other two will kill you. You think about it; it's true. If you hire somebody without the first, you really want them to be dumb and lazy.”

- Warren Buffett



Material Control & Accountability



- **Ensure the complete and timely knowledge of:**
 - What materials exist
 - Where the materials are
 - Who is accountable for them
- **Objective is NOT to detect whether something is missing. This could be impossible.**
- **The objective is to create an environment that discourages theft and misuse by establishing oversight.**
- **Most laboratories already control and track their samples for scientific reasons. The emphasis here is that this is also important from a security perspective.**





Information Security



- **Protect information that is too sensitive for public distribution**
- **Risks to information include**
 - Loss of integrity
 - Loss of confidentiality
 - Loss of availability
- **Biosecurity-related sensitive information**
 - Security of dangerous pathogens and toxins
 - E.g. Risk assessments
 - E.g. Security system design
 - Access authorizations

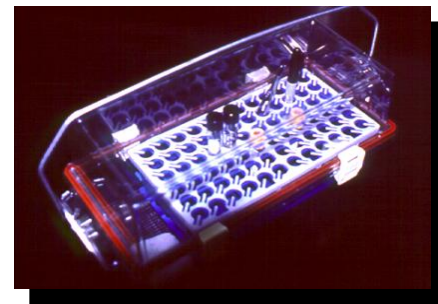




Internal Transport Security



- **Movement of materials to and from restricted areas within a facility**
- **May involve personnel from**
 - Labs
 - Shipping areas
 - Receiving areas
 - Disposal areas (e.g. autoclave and incinerator rooms)
- **Move materials safely and securely**
 - SOPs
 - Leak-proof containers
 - Pre-approval?
 - Chain of custody?





Group Discussion



Discuss: Does the laboratory biosafety concept of hierarchy of controls also apply to laboratory biosecurity?

Biosafety Hierarchy of Controls:

Elimination

Substitution

Engineered controls

Administrative controls

Personal protective equipment



Transportation Security and Export Controls



Ian Anthony
SIPRI



- **How do you identify risks?**
- **How do you manage risks?**
How do you decide which biosecurity mitigation measures to implement?
- **How do you know your management strategy is working?**



- **Biorisk is the combination of the probability of occurrence of harm and the severity of that harm where the source of harm is a biological toxin or agent**

The source may be an unintentional exposure, accidental release or loss, theft, misuse, diversion, unauthorized access, or intentional unauthorized release.

Biorisk is the integration of biosafety and biosecurity



The Biorisk AMP Model



**Biorisk Management =
Assessment + Mitigation + Performance**



Hazard ID
Risk Assessment



Biorisk Control Measures
Risk Management



Processes
QA/QC
Objectives



Group Activity



What criteria need to be considered when assessing laboratory biosecurity risks?

Write one criteria per sticky note.



Using the Risk Assessment to Manage Risks



For each of the following cases, which elements of biosecurity could have reduced the risk?



Biosecurity Cases: Theft of Pathogens



- **Limited evidence of attacks on bioscience facilities by outside adversaries with the intent to steal pathogens**

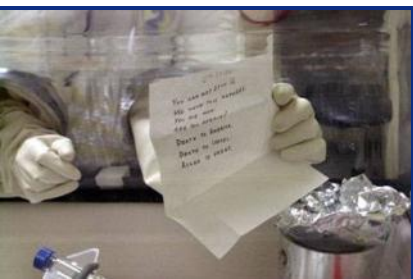
Only one recent example in the open literature—an attempted theft at the central reference laboratory for animal health in Indonesia targeted their pathogen collection

- **In contrast, there are many examples of people who work at bioscience facilities taking pathogens or toxins with the intent to commit malicious acts. For example,**

Mitsuru Suzuki—*Shigella dysenteriae* and *Salmonella typhi*, 1964-1966

Diane Thompson—theft of *Shigella dysenteriae* Type 2, Oct 1996

Bruce Ivins—Amerithrax, 2001





Biosecurity Cases: Theft of Intellectual Property



- **Illustrative examples**

Two former post-docs at Harvard Medical School indicted by grand jury for theft of research materials

- **Shipped 20 boxes of materials related to drug discovery research to new employer in Texas**

Post-doc at Cornell arrested with >250 test tubes, vials, and petri dishes in luggage before boarding a flight to Shanghai

- **Bacteria and yeast cultures for commercial enzyme production**





Security Cases: Attacks by Animal Rights Extremists



- **Illustrative examples**

Arson/sabotage

- **1987: ALF arson attack on UC Davis Animal Diagnostics Laboratory**
Damages: \$5.1 million, 1 building and 20 vehicles destroyed
- **1989: ALF sabotage of Texas Tech University**
Damages: \$700,000, destroyed records and computers
- **2002: ELF arson of University of Minnesota's Microbial and Plant Genomics Research Center while building was under construction**
Damages: \$250,000

Theft of animals

- **1987: Band of Mercy theft of infected cats from Beltsville Agricultural Research Center**
- **2005: ALF stole 10 – 21 mice and vandalized lab at Louisiana State University School of Veterinary Medicine**



Security Cases: Theft of General Property



- **Illustrative examples**

Former computer systems administrator for the Naval Research laboratory stole ~19,000 pieces of computer and office equipment over a ten year time period

Theft of \$86,000 worth of copper (reels of used cable, bopper blocks) from Brookhaven National Laboratory by an unknown adversary



Laboratory Biosecurity Program Management



- **Numerous stakeholders in program management**

- **All should:**

Ensure each component of biosafety and biosecurity are implemented and function optimally

Thoroughly understand and implement the risk assessment process

Decide which risks should be mitigated, and allocate resources accordingly

Clearly delineate the roles and responsibilities of laboratory personnel



Group Discussion



Define roles and responsibilities within an institution for laboratory biosecurity

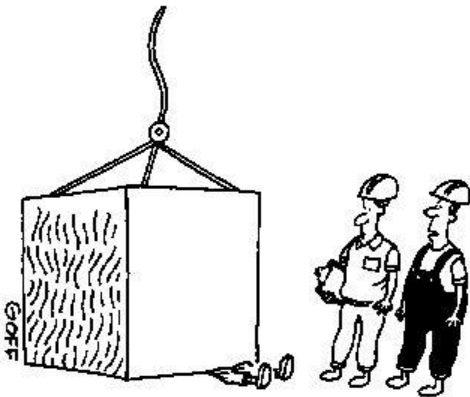
Consider analogies to laboratory biosafety:

Biosafety professional

Scientific manager / PI

Institutional Biosafety Committee

Top management



"It's worse than it looks.
That's the Safety Inspector."



Group Discussion



Laboratory Biosafety and Biosecurity

List 3 ways laboratory biosecurity potentially conflicts with biosafety

List 3 ways laboratory biosecurity supports biosafety

Biosafety

Biosecurity

**Biorisk
Management**



Group Discussion



- **What metrics do you use to measure the effectiveness of your laboratory biosafety program?**

Management performance indicators?

Operational performance indicators?

Status indicators?

- **Can the same metrics be used for biosafety and biosecurity?**



International Calls for Improving Laboratory Biosafety and Biosecurity



- **Organization for Economic Cooperation and Development, “Best Practice Guidelines for Biological Resource Centers,” published 2007**
- **Biological Weapons Convention Experts Group meetings in 2003 and 2008 address biosecurity**
- **United Nations Security Council Resolution 1540 (2004) requires States to establish and enforce legal barriers to acquisition of WMD by terrorists and states, including laboratory biosecurity measures**



International Calls for Biorisk Management



- **Laboratory Biorisk Management Standard**

Risk-based approach

CWA 15793:2008

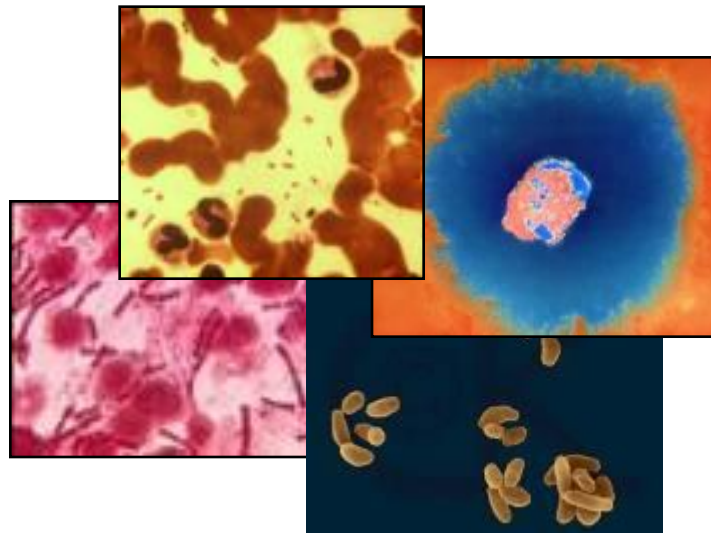


European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

- **World Health Organization Biorisk Reduction Program**

Addresses laboratory biosafety and biosecurity and infection control

For example, recently released laboratory handling guidance for H1N1





Group Discussion



For your country, write down:

- **Any dedicated biosecurity regulations**
- **Any aspects of biosecurity captured in other regulations**
- **Any aspects of biosecurity that are missing in your current regulatory environment**

Use the provided sticky notes

Strengthening Biological Risk Management



Vision for Integrated BioRisk Management:

- ✓ Increased focus on "awareness" to change current culture
- ✓ Clarify terminology
- ✓ Development of targeted "training strategies"
- ✓ Securing "commitment" from key stakeholders, including government officials, who must be on board
- ✓ Continue increasing "capacity" based on Regional/Country needs and establish accountability through development of Country "report cards"



Conclusions



- **Need to integrate biosafety and biosecurity considerations into decisions about laboratory operations**

Biosecurity is a key part of laboratory operations

- **Risk assessment is the fundamental resource allocation tool**

For making decisions about which risks need to be protected against

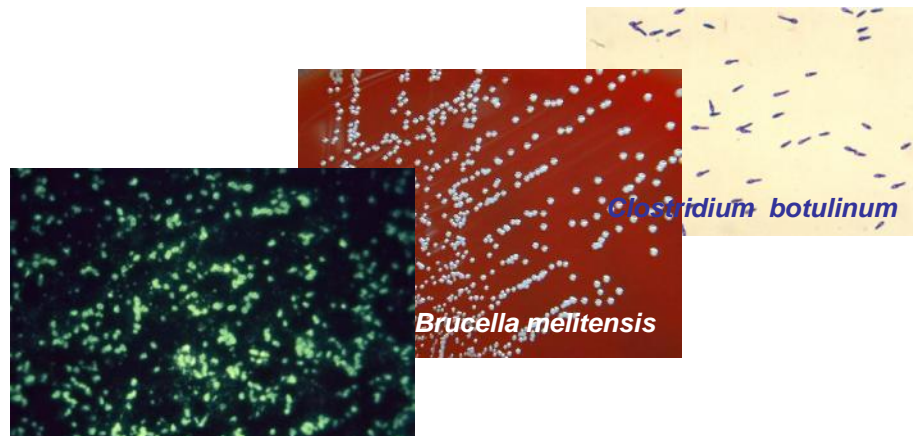
Graded protection

- **Program management is an overarching component of both biosafety and biosecurity programs**

Should address every element of the biosafety and biosecurity program

“Security precautions should become a routine part of laboratory work, just as have aseptic techniques and other safe microbiological practices.”

(WHO LBM 3rd edition)



Yersinia Pestis



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